

Rates of Radiolucency and Loosening After Total Shoulder Arthroplasty with Pegged or Keeled Glenoid Components

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Background: The objective of this study was to conduct a meta-analysis and cost-effectiveness analysis of the effect of glenoid design on radiolucency, loosening, and revision after total shoulder arthroplasty.

Methods: We conducted a systematic review of PubMed, MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, and CINAHL with use of a search for the terms arthroplasty AND shoulder AND (peg OR keel). Data on study design and on the end points of radiolucency, loosening, and revision were extracted independently and in duplicate. Random-effect models were used to calculate the pooled risk ratio and risk difference. The risk difference was used to estimate the number needed to treat (the number of individuals who would have to receive a pegged component to avoid one loosening or revision).

Results: Eight studies with a total of 1460 patients (mean age, sixty-seven years) were included. The mean study quality was 1.75 points (95% confidence interval [CI], 1.26 to 2.24) on the 3-point modified Jadad scale. There was no significant difference in the risk of any radiolucency (risk ratio, 0.42; 95% CI, 0.12 to 1.42) or in the risk of severe radiolucency (risk ratio, 0.65; 95% CI, 0.23 to 1.82) between pegged and keeled components. The pooled risk ratio for revision was 0.27 (95% CI, 0.08 to 0.88) in favor of pegged components ($p = 0.028$). At a cost-effectiveness threshold of \$50,000 per quality-adjusted life year, pegged components can be between \$2325 and \$40,920 more expensive than keeled components and still be cost-effective.

Conclusions: Our study produced evidence that pegged glenoid components were associated with a lower revision risk compared with keeled components. However, the difference was rather small and will therefore be most meaningful to high-volume shoulder arthroplasty centers. Because of the similarity between primary and secondary costs, pegged glenoid designs were more cost-effective than keeled glenoid designs.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

The number of total shoulder arthroplasties performed per year has grown substantially over recent years¹. It has been estimated that the number of primary total shoulder arthroplasties performed annually in the United States will grow from the present 20,000 to 100,000 around 2015 to 2020². Total shoulder arthroplasty can effectively reduce pain and improve shoulder mobility and function³⁻⁵. However, as with any arthroplasty, outcomes after total shoulder arthroplasty are jeopardized by complications such as postoperative

infection, periprosthetic fracture, and implant loosening. Glenoid loosening is among the most common indications for revision shoulder arthroplasty⁶⁻⁹. Since retrospective analysis of patients undergoing revision total shoulder arthroplasty has demonstrated radiolucent lines in up to 90% of such patients, a relationship between radiolucency and loosening has been postulated¹⁰.

Glenoid design has been identified as an important risk factor for component loosening. Early clinical studies and animal

Disclosure: None of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third party in support of any aspect of this work. One or more of the authors, or his or her institution, has had a financial relationship, in the thirty-six months prior to submission of this work, with an entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. No author has had any other relationships, or has engaged in any other activities, that could be perceived to influence or have the potential to influence what is written in this work. The complete **Disclosures of Potential Conflicts of Interest** submitted by authors are always provided with the online version of the article.

trials showed lower rates of loosening with pegged compared with keeled designs, but as cementing techniques have improved over time, loosening rates have improved for all implant designs¹¹⁻¹⁴. Edwards et al. found loosening rates of 0% for pegged and 15% for keeled designs, although this difference was not statistically significant, suggesting that the study was underpowered¹⁵. Gartsman et al. reported radiolucency in 5% of pegged glenoids and 39% of keeled glenoids¹⁶.

In the face of such conflicting results and underpowered research, meta-analysis may be a very helpful tool for collecting and assessing all available evidence. The objective of the present study was to systematically review and quantitatively synthesize the current literature comparing pegged and keeled glenoid designs.

Materials and Methods

This study follows the principles of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement¹⁷.

Systematic Literature Search

We systematically reviewed the literature with use of PubMed, MEDLINE, Embase, CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL). We searched these databases online for ("arthroplasty, replacement"[MeSH]) AND (shoulder) AND (cement OR cemented), using these terms both as keywords and as exploded MeSH terms, without restrictions in language or publication date.

We included only controlled studies directly comparing shoulder arthroplasty using pegged or keeled glenoid components in human subjects. Studies that had no focus on clinical outcome, involved animals or cadavers, or had unacceptably high attrition (>20%) during follow-up were excluded.

Extraction of Relevant Data

Eligibility of studies was assessed independently and in duplicate, and the assessments were then crosschecked. The bibliographies of all included studies were reviewed for additional relevant studies. All searches were concluded by November 1, 2011.

The variables that were extracted independently and in duplicate to describe study quality were study size, patient age, percentage of female patients, level of evidence (I through V), randomization (yes or no), blinding (yes or no), attrition (yes or no), and power (yes or no). The extracted outcome data were radiolucency, loosening, and revision. Radiolucency was further subdivided into "any radiolucency" and "severe radiolucency," with severe radiolucency defined as a grade of at least 3 according to the system developed by Franklin et al.¹⁸⁻²⁰ (see Appendix and Fig. 1).

Assessment of Internal Validity and Risk of Bias

The level of evidence and internal validity of each included study were determined with use of a modified Jadad scale, on which 1 point was assigned for randomization, 1 for blinding, and 1 for attrition (0 points = poorest total score, and 3 points = best total score)²¹. An additional quality parameter involved whether or not the authors reported conducting an a priori sample size calculation.

Assessment of Publication Bias

An important problem that affects the validity of meta-analyses is publication (or "file-drawer") bias, which is bias attributable to unidentified or unpublished studies²²⁻²⁴. Publication bias among the included studies was assessed graphically with use of funnel plots and mathematically with use of Egger weighted regression²⁵.

Assessment of Heterogeneity Among Studies

The presence of heterogeneity among the included studies was assessed qualitatively with use of the Cochran Q test and quantitatively with use of the I^2 index²⁶⁻²⁸. Because of the low power of the former test in small samples, a p value of up to 0.1 was taken to indicate significant heterogeneity.

Quantitative Data Synthesis

All calculations were performed with use of Intercooled Stata 12 (StataCorp, College Station, Texas). A p value of 0.05 was considered significant for the pooled estimates.

Pooling of the data was performed by use of the DerSimonian-Laird method to construct random-effects models²⁹. Such models postulate that the observed heterogeneity among studies in a meta-analysis is attributable to effects in individual studies that are normally distributed around a common effect. This assumption was assessed graphically with use of forest plots.

Pooled risk ratios were calculated to compare pegged and keeled components. Pooled risk differences were also calculated for the clinically more severe end points of loosening and revision. The risk difference (RD) is the difference in the risk of loosening or revision between pegged and keeled components. Each risk difference was then used to calculate the number needed to treat (NNT = 1/RD). The number needed to treat is the number of patients who would have to receive a pegged component in order to prevent one loosening or one revision.

In addition, the "metainf" routine in Stata was used to evaluate the influence of larger studies. This algorithm repeats a meta-analysis omitting one study at a time and compares the pooled results. If the omission of a particular study results in a significantly different pooled result compared with the results of the full model that included all studies, then that study is considered to be "influential."

Cost-Effectiveness Analysis

Treatment costs, in the form of national mean Medicare reimbursements (based on the relevant Common Procedural Terminology and Diagnosis-

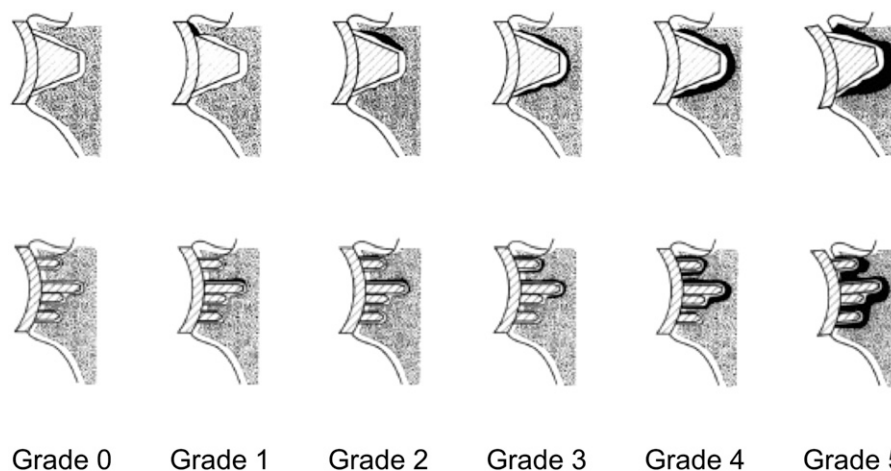


Fig. 1
The Franklin grading system for loosening of keeled and pegged glenoid components. (Reproduced, with modification, from: Lazarus MD, Jensen KL, Southworth C, Matsen FA 3rd. The radiographic evaluation of keeled and pegged glenoid component insertion. J Bone Joint Surg Am. 2002 Jul;84[7]:1174-82.)

Related Group codes and including professional fees but not implant costs) expressed in 2011 U.S. dollars, were obtained from the literature. Data on utility and quality-adjusted life years (QALYs) lost because of loosening or revision were also obtained from the literature. Since we were not able to find data for the cost difference between pegged and keeled components, we calculated the “headroom” for pegged components over keeled components—i.e., how much more or less money pegged components could cost while still being more cost-effective than keeled components. An incremental cost-effectiveness ratio of <\$50,000 per QALY, as suggested by Britain’s National Institute for Health and Clinical Excellence (NICE), was used in this calculation.

Source of Funding

No funding was obtained for this study.

Results

Study Characteristics

Our online search strategy identified 131 studies, seven of which satisfied the inclusion criteria. One additional study was identified from the reference lists of the identified studies, resulting in a total of eight included studies^{12,13,15,16,30,32-34} (Fig. 2). A study by Roche et al. came close to meeting the eligibility criteria but was not included because the loosening data were generated in a laboratory model³¹. The included studies were all published between 2002 and 2010 in the English language (see Appendix). A total of 1460 patients with a mean age of sixty-seven years were included.

Description of the Included Studies

Edwards et al.¹⁵ published a prospective randomized study on the effect of glenoid design on loosening after total shoulder arthroplasty involving the polyethylene Aequalis Total Shoulder

der prosthesis (Tornier, Montbonnot, France) and modern cementing. Forty-seven patients with primary osteoarthritis were randomized to receive a pegged or a keeled glenoid component. The pegged component had one central peg and three peripheral pegs. Three blinded assessors graded radiolucency annually for two years with use of the Franklin grading system (see Appendix). Clinical complications and treatment failures were also recorded at these times.

Throckmorton et al.³⁰ reported on 100 patients treated for primary osteoarthritis with cemented polyethylene components (Smith & Nephew, Memphis, Tennessee). Fifty glenoid components were pegged, with three pegs in a line, and fifty were keeled. Radiographs made at a minimum follow-up of two years were assessed by four investigators for radiolucent lines in five different areas.

Two studies involved the cemented polyethylene Cofield 2 prosthesis (Smith & Nephew). In 2009, Fox et al.³⁴ reported on a prospective study of the survival of 1542 total shoulder arthroplasties (including 497 with a keeled glenoid and 358 with a pegged glenoid) in 1337 patients at one, two, and five years. Clinical outcomes such as revision surgery were also recorded at these times. In 2005, Gartsman et al.¹⁶ compared twenty pegged and twenty-three keeled components. An a priori power analysis was conducted prior to the study. Observers graded radiolucency with use of the Franklin scale.

Rahme et al.³² published a prospective, randomized controlled study involving cemented polyethylene Bigliani/Flatow prostheses (Zimmer, Warsaw, Indiana). Fourteen glenoid components had three pegs, and thirteen were keeled. Clinical scores and radiographic scores using the Franklin system were documented at four months, one year, and two years.

Three studies used the cemented polyethylene GLOBAL Shoulder Arthroplasty System (DePuy, Warsaw, Indiana), which has one central and four peripheral pegs on the pegged component. In 2007, Nuttall et al.³³ published the results of a prospective randomized study of ten keeled compared with ten pegged components; clinical and radiographic results were assessed at up to two years. Trail and Nuttall¹³ reported on twenty-nine pegged and eleven keeled glenoid components in patients with rheumatoid arthritis; radiographic and clinical results were assessed at up to six years postoperatively. Although this study involved patients with rheumatoid arthritis, we found no statistical evidence for a difference between these patients and the patients with osteoarthritis in the other studies. The earliest comparative study was published in 2002 by Lazarus et al.¹², who reviewed postoperative radiographs of 289 pegged and thirty-nine keeled components with use of the Franklin system.

Study Quality

The mean Jadad score for the included trials was 1.75 points (95% confidence interval [CI], 1.26 to 2.24 points). Five of the eight studies used a randomized design, but only two reported the use of blinded outcome assessment. Three studies report an a priori sample size calculation (see Appendix).

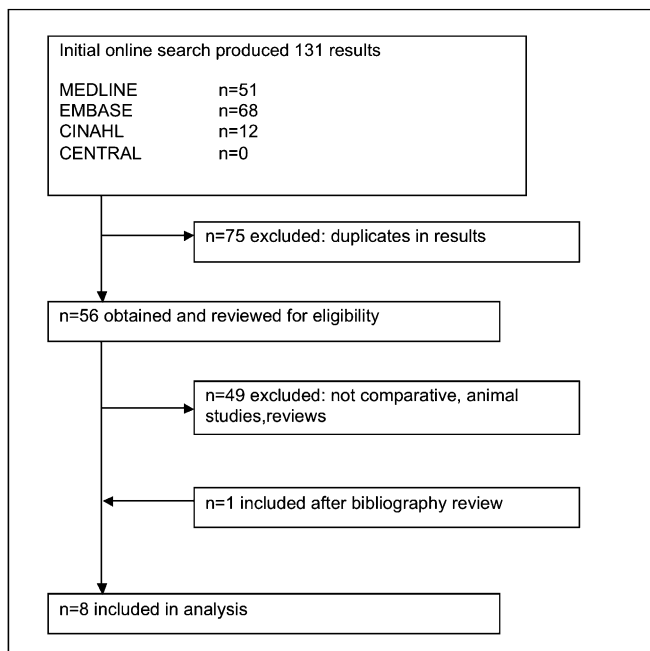


Fig. 2
Identification and inclusion of studies.

Publication Bias

The funnel plots for all end points were symmetrical, indicating no evidence of publication bias. Mathematically, there was no evidence of publication bias for radiolucency ($p = 0.068$), postoperative complications ($p = 0.486$), or revision ($p = 0.558$).

Heterogeneity

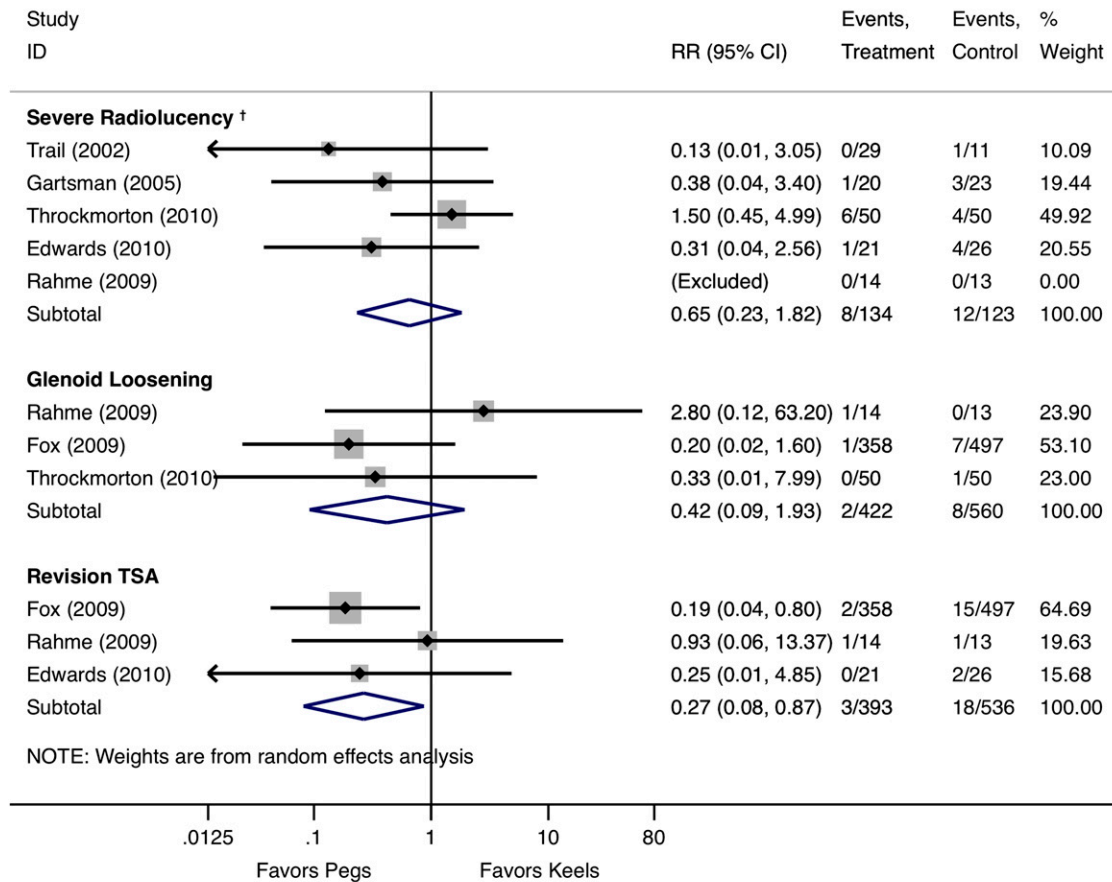
Heterogeneity among the studies was high ($I^2 = 73.9\%$, $p = 0.004$) for radiolucency. However, as shown in the forest plot, all studies were normally distributed around a common effect, suggesting that the random-effect model could indeed be used to pool the individual results. There was no significant heterogeneity among studies for loosening (I^2 index = 13.6% , $p = 0.324$) or revision ($I^2 = 0\%$, $p = 0.609$).

Pooled Effect

The pooled risk ratio for any radiolucency around pegged compared with keeled components was 0.42 (95% CI, 0.12 to 1.42), which was not significant ($p = 0.160$). The risk ratio for severe radiolucency was 0.65 (95% CI, 0.23 to 1.82), which was also not significant ($p = 0.414$). The risk difference for severe radiolucency was -0.03 (95% CI, -0.09 to 0.04) (Fig. 3).

The pooled risk ratio for loosening of pegged compared with keeled components was 0.42 (95% CI, 0.09 to 1.93; $p = 0.652$). The risk difference for loosening was -0.01 (95% CI, -0.02 to 0.00) in favor of pegged components, which was of borderline significance ($p = 0.051$). The corresponding 95% CI for the number needed to treat was forty-four to 14,644.

Radiolucencies, Loosenings, and Revisions risk ratio by glenoid design



† see text for definition

Fig. 3
Forest plot representing the findings of the meta-analysis for the end points of severe radiolucency, loosening, and revision total shoulder arthroplasty (TSA). The “treatment” group represents pegged components, and the “control” group represents keeled components. Severe radiolucency was defined as either a grade of at least 3 according to the system developed by Franklin et al.¹⁸ or circumferential radiolucency that was ≥ 1.5 mm in width at some point^{19,20}. If the diamond indicating the pooled result overlaps the vertical black line at a risk ratio (RR) of 1, the difference is not significant. The impact of the glenoid design increases from top (severe radiolucency) to bottom (revision) as the pooled effect increasingly favors pegged components.

The pooled risk ratio for revision was 0.27 (95% CI, 0.08 to 0.87) in favor of pegged components, which was significant ($p = 0.028$). The risk difference between pegged and keeled components was -0.03 (95% CI, -0.04 to -0.01), which was significant ($p = 0.003$). The corresponding 95% CI for the number needed to treat was twenty-three to 115.

We analyzed the influence of larger studies on the radiolucency and loosening rates. In no case did removal of a study result in a statistically significant change in these results. However, omission of the study by Fox et al.³⁴, with 855 patients, led to a shift of the pooled risk ratio for revision from 0.27 (95% CI, 0.08 to 0.88) to 0.95 (95% CI, 0.06 to 16.4).

Cost-Effectiveness Analysis

The mean cost of primary total shoulder arthroplasty in the United States is \$12,270 (in 2011 dollars), and the mean cost of revision total shoulder arthroplasty is \$12,508³⁵. We found no evidence for a difference in cost between pegged and keeled components. The QALY values were calculated as (utility of the implant) \times (number of years with the implant). The utility has been estimated to be 0.9 after primary total shoulder arthroplasty, -0.2 for the year after a revision procedure, and 0.8 thereafter³⁵. However, the studies on which these estimates were based rarely reported on any outcomes beyond ten years of follow-up; thus, the utility was reduced by 50% beyond that time point to account for wear and tear on the implant and aging³⁵. The mean age of the patients included in the present study was sixty-seven years; thus, assuming a mean life expectancy of eighty years in Western countries (according to World Bank data), the included patients would spend a mean of thirteen years with the implant. This translates into a mean QALY gain of 10.35 (0.9 utility \times [10 years + 50% \times 3 years]) because of primary total shoulder arthroplasty.

All revisions and loosening analyzed in this study had occurred by two years of follow-up. Thus, for cases of revision arthroplasty, we added together (1) two years of the utility for a healthy total shoulder arthroplasty (0.9), (2) one year of disutility (-0.2) because of the revision, and (3) the remaining ten years of the reduced utility of a revised implant (0.8). The resulting mean QALY was 9.6, which was 0.93 less than that for an arthroplasty that was not revised. On the basis of the results of our meta-analysis, the relative revision risk for pegged compared with keeled components was 0.08 to 0.88, resulting in a difference of 0.074 to 0.82 QALY. At an incremental cost-effectiveness ratio of \$50,000 per QALY, pegged components would have headroom of \$2325 to \$40,920 over keeled components while still being cost-effective.

Discussion

The current evidence indicates better results for total shoulder arthroplasty with pegged compared with keeled glenoid components. A closer analysis of the specific differences suggests that at least some of the reasons involve factors other than radiolucency. This is based on the observation that there was no significant difference in the rate of radiolucency between the two groups, whereas there was strong evidence for a difference in

impact of the two glenoid designs on loosening and revision rates.

It should be considered that the progression from radiolucency to loosening to revision is not fully proven. Radiolucency has been associated with revision of total shoulder arthroplasty; however, radiolucency is quite common even immediately postoperatively, and a causal relationship or a common cause leading to radiolucency and loosening has yet to be identified¹². Lazarus et al. reviewed data on 328 patients and found a radiolucency rate of 51% on the initial postoperative radiographs compared with 64% at a follow-up of two years and more¹². In the present meta-analysis, the association between glenoid design (pegged or keeled) and revision was much stronger than that between design and radiolucency. This finding is in agreement with previously reported results by Lazarus et al. that indicated only a weak association ($r^2 = 0.13$) between radiolucency and glenoid seating¹². A similar discontinuity between the occurrence of radiolucency and that of loosening has also been shown in other joints. Sadoghi et al. found a strong association between radiolucent lines and pain and between radiolucent lines and cementing technique, but not between loosening and revision, in total knee arthroplasty³⁶.

Our data indicated that one revision could be avoided for every twenty-three to 115 implanted glenoids that are pegged instead of keeled. In comparison, the number-needed-to-treat value for use of low-molecular-weight heparin or warfarin compared with placebo after total hip arthroplasty has been estimated to be ten to fifty³⁷. A range of twenty-three to 115 patients might be a fairly high number for an individual shoulder surgeon. In recent studies, surgeons qualified as "high-volume" if they performed more than five procedures per year^{38,39}, although this number has probably increased since these data were published in 2003 and 2005.

Nevertheless, a number-needed-to-treat value in the range of twenty-three to 115 is very meaningful from an epidemiological point of view. Also, hospitals that employ more than one shoulder surgeon will have higher volumes than individual surgeons. Lyman et al. assessed total shoulder arthroplasty outcomes according to hospital volume rather than surgeon volume and reported that approximately one-half of the 1300 procedures performed in the state of New York from 1996 to 1999 were performed at the five highest-volume hospitals⁴⁰. A similar study by Jain et al. provided nationwide data and showed that an order volume of twenty-three to 115 shoulder implants was not unusual for purchasing departments at most of these hospitals⁴¹. As mentioned above, it is estimated that the number of total shoulder arthroplasties performed annually in the United States will grow to 100,000 around 2015 to 2020². This growing patient population will further increase the total shoulder arthroplasty volume for both surgeons and hospitals. One group that is particularly affected by these results is biomedical device companies, which have seen strong growth in total shoulder implant sales and have sale volumes that are much larger than the number-needed-to-treat value of twenty-three to 115. In light of recent recalls of prosthetic components, such as the ASR hip system (DePuy, Warsaw, Indiana) in 2010,

it would seem prudent to consider the increased risk of revision of keeled compared with pegged components.

Our cost-effectiveness analysis showed that pegged components dominated keeled components. This was primarily because of the virtually identical costs of the two primary procedures and the additional cost incurred during the treatment of complications. As emphasized above, the risks of loosening and revision surgery are low enough that it is primarily high-volume surgeons who will be confronted with these problems. Nevertheless, because of the equivalent secondary cost, pegged components would be cost-effective even at a price difference of up to approximately \$40,000.

This calculation was based on the recommendation that any incremental cost-effectiveness ratio of <\$50,000 per QALY be considered cost-effective. That number is commonly used in cost-effectiveness analyses and is based on the threshold of £30,000 per QALY estimated by Britain's NICE. That threshold value was established by assessing the health-care system's willingness to pay, but it should be considered more of an approximate estimate than a precise calculation. Nevertheless, pegged components would remain more cost-effective than keeled components even if that value were substantially reduced.


Our study has potential shortcomings. As in all meta-analyses, the validity of our findings depends on the validity of the included primary studies. Their overall study quality, however, was fairly high, suggesting a limited risk of bias. The number of included patients in one very large study by Fox et al.³⁴ was almost ten times greater than the mean number in the other studies in the meta-analysis. However, we found no evidence that this study had an undue influence on our findings. Thus, although its results were weighted more heavily, the pooled risk ratio would not have been different if numerous smaller studies had contributed the same total number of patients.

Another shortcoming is the low interobserver reliability of the assessment of radiolucent lines¹². This is reflected in the mathematical heterogeneity of the radiolucency results among the included primary studies. However, this heterogeneity was normally distributed around a common effect, suggesting that there was no systematic deviation from the true value (i.e., no bias) and allowing pooling with a random-effect model. It should be noted that the other end points of loosening and

revision, which were clinically more meaningful and more obvious, were assessed independently and showed no evidence of significant heterogeneity.

In conclusion, our study produced evidence that pegged glenoid components were associated with less frequent loosening and revision compared with keeled components. However, these differences were rather small and will therefore be most meaningful to high-volume shoulder arthroplasty centers. Because of the similarities in primary and secondary costs between the designs, pegged designs dominated keeled designs in a cost-effectiveness analysis.

Appendix

 Tables summarizing the Franklin grading system and the characteristics and designs of the included studies are available with the online version of this article as a data supplement at jbjs.org. ■

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